BSD MEDICAL CORP Form 424B5 May 03, 2010

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Prospectus Supplement (To Prospectus Dated October 1, 2009)

# BSD MEDICAL CORPORATION 1,644,737 SHARES OF COMMON STOCK WARRANTS TO PURCHASE 1,233,553 SHARES OF COMMON STOCK 1,233,553 SHARES OF COMMON STOCK ISSUABLE UPON EXERCISE OF THE WARRANTS

We are offering directly to selected investors up to 1,644,737 shares of our common stock and warrants to purchase up to 1,233,553 shares of our common stock (including 1,233,553 shares of common stock issuable upon exercise of the warrants) pursuant to this prospectus supplement and the accompanying prospectus. Of the 2,878,290 shares of common stock offered hereby, 1,233,553 shares are issuable upon exercise of the warrants. The securities will be sold in multiples of a fixed combination consisting of one share of common stock and a warrant to purchase 0.75 shares of common stock, at an initial exercise price of \$1.94. Each fixed combination will be sold at a negotiated price of \$1.52 per fixed combination. The warrants will be exercisable on or after the date that is six months and one day after the date the warrants are issued and will expire on the fifth anniversary of the date the warrants become exercisable.

For a more detailed description of the common stock and warrants, see the section entitled "Description of Securities We Are Offering" beginning on page S-11.

Our common stock is traded on The NASDAQ Global Market under the symbol "BSDM". On April 30, 2010, the last reported sale price for our common stock was \$1.85 per share. There is no established public trading market for the warrants, and we do not expect a market to develop. We do not intend to apply to list the warrants on any securities exchange.

As of April 30, 2010, the aggregate market value of our outstanding common equity held by non-affiliates was approximately \$27,196,317 based on 14,700,712 shares of outstanding common stock held by non-affiliates and a price of \$1.85 per share, which was the last reported sale price of our common stock on The Nasdaq Global Market on April 30, 2010. Within the prior 12 calendar month period that ends on, and includes the date of this prospectus supplement, we have sold securities in the amount of \$3,632,356 pursuant to General Instruction I.B.6. of Form S-3. The value of the securities offered hereby is \$4,782,073.

We have retained Roth Capital Partners LLC as our exclusive placement agent in connection with this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of securities. See "Plan of Distribution" beginning on page S-13 of this prospectus supplement for more information regarding these arrangements.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page S-3 of this prospectus supplement and "Risk Factors" beginning on page 5 of the accompanying prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Fixed Combination of one share of common stock and one warrant to purchase 0.75 shares of	
	common stock	Total
Public Offering Price	\$ 1.52	\$ 2,500,000
Placement agency fees	\$ .10	\$ 162,500
Proceeds, before expenses, to us	\$ 1.42	\$ 2.337.500

Roth Capital Partners, LLC is acting as the exclusive placement agent in this offering. We estimate the total expenses of this offering, excluding the placement agency fees, will be approximately \$65,000. Because there is no minimum offering amount, the actual offering amount, the placement agency fees and net proceeds to us, if any, in this offering may be substantially less than the total offering amounts set forth above. We are not required to sell any specific number or dollar amount of the securities offered in this offering, but the placement agent will use its reasonable efforts to arrange for the sale of all of the securities offered.

Delivery of the securities will be made on or before May 6, 2010.

**Roth Capital Partners** 

The date of this prospectus supplement is May 3, 2010

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#### ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus are part of a "shelf" registration statement on Form S-3, registration statement number 333-162080, that we filed with the Securities and Exchange Commission (the SEC) on September 23, 2009 and that was declared effective on October 1, 2009. Under this shelf registration process, we may offer and sell from time to time in one or more offerings the securities described in the accompanying prospectus. This prospectus supplement describes the specific details regarding this offering, including the price, the amount of our common stock and warrants being offered, the risks of investing in our common stock, warrants and other items.

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of our common stock and warrants and also adds, updates, and changes information contained in the accompanying prospectus and the documents incorporated by reference. The second part is the accompanying prospectus, which gives more general information, some of which may not apply to this offering. Generally, when we refer to this "prospectus," we are referring to both documents combined. To the extent the information contained in this prospectus supplement differs or varies from the information contained in the accompanying prospectus or any document filed prior to the date of this prospectus supplement and incorporated by reference, the information in this prospectus supplement will control.

You should rely only on the information contained in this prospectus supplement and the accompanying prospectus, including any information incorporated by reference. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. You should not assume that the information appearing in this prospectus, any prospectus supplement or any document incorporated by reference is accurate at any date other than as of the date of each such document. Our business, financial condition, results of operations and prospects may have changed since the date indicated on the cover page of such documents.

References in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference to "we," "our," "us," "BSD" and "the Company" refer to BSD Medical Corporation. Both this prospectus supplement and the accompanying prospectus include important information about us, our common stock and other information you should know before investing. This prospectus supplement also adds, updates, and changes certain of the information contained in the prospectus. You should read both this prospectus supplement and the accompanying prospectus as well as the additional information described under the headings "Where You Can Find More Information" and "Incorporation by Reference" before investing in our common stock and warrants.

This prospectus supplement contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus supplement is a part, and you may obtain copies of those documents as described below under the heading "Where You Can Find More Information."

# PROSPECTUS SUPPLEMENT SUMMARY

This summary is not complete and does not contain all of the information that you should consider before investing in the securities offered by this prospectus. You should read this summary together with the entire prospectus supplement and prospectus, including our financial statements, the notes to those financial statements and the additional information described in this prospectus supplement under the headings "Where You Can Find More Information" on page S-15 and "Incorporation by Reference" on page S-15, before making an investment decision. See

the "Risk Factors" section of this prospectus supplement beginning on page S-3 for a discussion of the risks involved in investing in our securities.

# Summary of Our Business

We develop, manufacture, market and service medical systems that deliver precision-focused radio frequency (RF) or microwave energy into diseased sites of the body, heating them to specified temperatures as required by a variety of medical therapies. Our business objectives are to commercialize our products developed for the treatment of cancer and to further expand our systems to treat other diseases and medical conditions. Our product line for cancer therapy has been created to offer hospitals and clinics a complete solution for thermal treatment for cancer provided through microwave/RF systems.

While our primary developments to date have been cancer treatment systems, we also pioneered the use of microwave thermal therapy for the treatment of symptoms associated with enlarged prostate, and we are responsible for technology that has contributed to a new medical industry addressing the needs of men's health. In accordance with our strategic plan, we subsequently sold our interest in TherMatrx, Inc., the company established to commercialize our technology to treat enlarged prostate symptoms, to provide substantial funding that we can utilize for commercializing our systems used in the treatment of cancer and in achieving other business objectives.

Our product line includes systems that have been strategically designed to offer a range of thermal treatment systems for the treatment of cancer, including both hyperthermia and ablation treatment systems. Studies have shown that both hyperthermia and ablation treatments kill cancer but they have different clinical applications.

Our hyperthermia cancer treatment systems are used to treat cancer with heat (hyperthermia) while boosting the effectiveness of radiation through a number of biological mechanisms. Hyperthermia is usually used to increase the effectiveness of other therapies; e.g., radiation therapy and chemotherapy for the treatment of locally advanced cancers. Hyperthermia usually refers to treatments delivered at temperatures of 40-49°C for one hour.

Our microwave ablation system is to be used to ablate (remove or vaporize) soft tissue with heat alone. Thermal ablation usually refers to heat treatments delivered at temperatures above 55°C for short periods of time. Thermal ablation is used to destroy local tumors using a short intense focus of heat on a specific area, which is usually small, similar to surgical removal of the tumor.

Our primary mission is to develop the full spectrum of medical uses for our special competence in precision-focused RF/microwave systems, and to broadly apply the utilization of our technology to treat cancer and benign diseases and conditions.

Our principal executive offices are located at 2188 West 2200 South, Salt Lake City, Utah 84101, and our telephone number is (801) 972-5555.

On April 22, 2008, we changed the listing of our stock from the American Stock Exchange (AMEX) to the NASDAQ Stock Market (NASDAO), and our stock now trades under the NASDAO symbol "BSDM."

#### The Offering

Common stock offered by us Common Stock outstanding after 24,860,509 shares this offering (assuming no

exercise of the warrants offered

by us)

Warrants offered by us

1.644,737 shares

Warrants to purchase up to 1,233,553 shares of common stock. Each warrant may be exercised at any time on or after the date that is six months and one day after the date the warrants are issued until the fifth anniversary of the date the warrants become exercisable at an initial exercise price of \$1.94 per share of common stock, subject to adjustment. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants.

Use of proceeds We intend to use the net proceeds from this offering for

general corporate purposes, including working capital, subject to any agreed upon contractual restrictions under the terms of the purchase agreement. See "Use of

Proceeds" on page S-10.

warrants

Market for the common stock and Our common stock is quoted and traded on the

NASDAQ Global Market under the symbol "BSDM." However, there is no established public trading market

for the offered warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list

the warrants on any securities exchange.

You should read the "Risk Factors" section of this Risk Factors

prospectus supplement and in the documents

incorporated by reference in this prospectus supplement for a discussion of factors to consider before deciding to

purchase our securities.

NASDAQ Global Market Symbol BSDM

The number of shares of common stock to be outstanding after this offering as reflected in the table above is based on the actual number of shares outstanding as of April 30, 2010, which was 23,215,772, and does not include, as of that date:

- ·573,825 shares of our common stock issuable upon the exercise of outstanding stock options under our Fourth Amended and Restated 1998 Director Stock Plan, having a weighted average exercise price of \$5.18 per share;
- ·486,952 shares of our common stock reserved for future issuance under our Fourth Amended and Restated 1998 Director Stock Plan;
- ·1,938,462 shares of our common stock issuable upon the exercise of outstanding stock options under our Third Amended and Restated 1998 Stock Incentive Plan, having a weighted average exercise price of \$2.91 per share;
- ·3,082,329 shares of our common stock reserved for future issuance under our Third Amended and Restated 1998 Stock Incentive Plan;
- ·882,345 shares of our common stock issuable upon the exercise of warrants, at an exercise price of \$2.04 per share; and
- $\cdot$ 1,233,553 shares of common stock issuable upon the exercise of warrants to be issued in this offering, at an exercise price of \$1.94 per share.

Unless otherwise stated, outstanding share information throughout this prospectus supplement excludes such outstanding options and warrants to purchase shares of common stock and shares available for issuance.

#### **RISK FACTORS**

Before you make a decision to invest in our securities, you should consider carefully the risks described below, together with other information in this prospectus supplement, the accompanying prospectus and the information incorporated by reference herein and therein. If any of the following events actually occur, our business, operating results, prospects or financial condition could be materially and adversely affected. This could cause the trading price of our common stock to decline and you may lose all or part of your investment. The risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also significantly impair our business operations and could result in a complete loss of your investment.

## RISKS RELATED TO THIS OFFERING

Since we have broad discretion in how we use the proceeds from this offering, we may use the proceeds in ways with which you disagree.

We have not allocated specific amounts of the net proceeds from this offering for any specific purpose. Accordingly, subject to any agreed upon contractual restrictions under the terms of the purchase agreement, our management will have significant flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and subject to any agreed upon contractual restrictions under the terms of the purchase agreement, you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

There is no minimum offering amount required to consummate this offering.

There is no minimum offering amount which must be raised in order for us to consummate this offering. Accordingly, the amount of money raised may not be sufficient for us to meet our business objectives. Moreover, if only a small amount of money is raised, all or substantially all of the offering proceeds may be applied to cover the offering expenses and we will not otherwise benefit from the offering. In addition, because there is no minimum offering amount required, investors will not be entitled to a return of their investment if we are unable to raise sufficient proceeds to meet our business objectives.

You will experience immediate dilution in the book value per share of the common stock you purchase.

Because the price per share of our common stock being offered is substantially higher than the book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. After giving effect to the sale by us of 1,644,737 shares of common stock in this offering, and based on a public offering price of \$1.52 per fixed combination in this offering and a pro forma net tangible book value per share of our common stock of \$0.51 as of February 28, 2010, without giving effect to the potential exercise of the warrants being offered by this prospectus supplement, if you purchase securities in this offering, you will suffer immediate and substantial dilution of \$1.01 per share in the net tangible book value of the common stock purchased. See "Dilution" on page S-10 for a more detailed discussion of the dilution you will incur in connection with this offering.

There is no public market for the warrants to purchase common stock in this offering.

There is no established public trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the warrants on any securities exchange. Without an active market, the liquidity of the warrants will be limited.

### RISKS RELATED TO OUR COMPANY

We have a history of significant operating losses and such losses may continue in the future.

Since our inception in 1978, our expenses have substantially exceeded our revenue, resulting in continuing losses and an accumulated deficit of \$20,540,840 at February 28, 2010. We reported net losses of \$11,384,870, \$2,439,099 and \$3,348,195 in fiscal years 2009, 2008 and 2007, respectively.

We may continue to incur operating losses in the future as we continue to incur costs to develop our products, protect our intellectual property and expand our sales and marketing activities. To become profitable we will need to increase significantly the revenues we receive from sales of our hyperthermia therapy products and to successfully commercialize our new ablation product to improve our profitability on a quarterly or annual basis. We have been unable to do this in the past and we may be unable to do so in the future, and therefore may never achieve profitability.

Adverse worldwide economic conditions have made it difficult for our customers to obtain approval for the purchase of and funding for our hyperthermia systems.

Our hyperthermia cancer treatment systems represent capital equipment purchases for our customers. Adverse worldwide economic conditions have made it difficult for our customers to obtain approval for the purchase of and funding for our hyperthermia systems. This has contributed to a lack of growth in our worldwide sales of our systems. To the extent that adverse economic conditions continue, we believe our sales of hyperthermia systems will

continue to be negatively impacted and possibly decrease in fiscal year 2010 as compared to fiscal year 2009.

Our revenues can fluctuate significantly from period to period because our sales, to date have been based upon a relatively small number of systems, the sales price of each being substantial enough to greatly impact revenue levels in the periods in which they occur.

Our revenues can fluctuate significantly from period to period because our sales, to date, have been based upon a relatively small number of hyperthermia systems, the sales price of each being substantial enough to greatly impact revenue levels in the periods in which they occur. Sales of a few systems, particularly BSD-2000/3D/MR systems, can cause a large change in our revenues from period to period and the sales cycle for our systems generally extends over multiple financial reporting periods. In addition, differences in the configuration of the systems sold, pricing, and other factors can result in significant differences in the sales price per system and in the total revenues reported in a given period. As a result, there may be quarterly financial reporting periods where we may report no or minimal revenues from the sale of hyperthermia systems.

A significant portion of our revenues have been from related parties, and we have had significant concentrations of revenues in foreign countries.

During the years ended August 31, 2009, 2008, and 2007, we had sales of \$603,000, \$2,809,132 and \$1,385,332, respectively, to entities controlled by a significant stockholder and member of the Board of Directors. These related party transactions represent 17%, 55% and 49% of total sales for each respective year.

A significant portion of our revenues are derived from sales to foreign customers. During the years ended August 31, 2009, 2008 and 2007, export sales totaled \$1,668,547, \$2,812,796 and \$1,787,363, or 47%, 55% and 63% of total sales, respectively. During fiscal year 2009, export sales to China, Switzerland and Poland were approximately 16%, 13% and 14% of total sales, respectively. During fiscal years 2008 and 2007, export sales to Switzerland were approximately 53% and 44% of total sales, respectively.

To the extent that we are unable to maintain or increase the level of our revenues derived from related parties or foreign customers, the results of our operations could be negatively impacted.

Our hyperthermia therapy products may not achieve market acceptance which could limit our future revenue and ability to achieve profitability.

To date, hyperthermia therapy has not gained wide acceptance by cancer-treating physicians. We believe this is due in part to the lingering impression created by the inability of early hyperthermia therapy technologies to focus and control heat directed at specific tissue locations and conclusions drawn in early scientific studies that hyperthermia was only marginally effective. Additionally, market acceptance depends upon physicians and hospitals obtaining adequate reimbursement rates from third-party payors to make our products commercially viable, and we believe that reimbursement rates have not been adequate to stimulate strong interest in adopting hyperthermia as a new cancer therapy. If our sales and marketing efforts to promote hyperthermia therapy acceptance in the medical community fail, or our efforts to improve third-party reimbursement rates for hyperthermia therapy are not successful, then our future revenue from sales of our products may be limited, and we may never be able to obtain profitable recurring operations.

We have delayed market introduction of our MTX-180 ablation product and are unable to predict when design modification, marketing and sales strategies will be completed or when regulatory approval will be obtained.

Our MTX-180 Microwave Ablation System represents a major part of our business plan moving forward. The FDA granted us a 510(k) clearance to market the MTX-100, which authorizes the commercial sale of the device in the United States. Since receipt of FDA clearance to market the MTX¬100, we have devoted significant efforts to optimizing the design of the system to improve its ease of use and its medical applications. Following clinical evaluations of Phase I, we decided to postpone market entry until completion of the optimized Phase II design, the MTX-180. We believe this will allow us to enter this market with an optimized system that will have a wider range of clinical applications and increased revenue streams.

Additional time will be required to complete the market-ready Phase II design, apply for applicable regulatory approvals, and finalize the manufacturing processes for the MTX-180 and the applicators. Also, final marketing and sales strategies must be completed prior to market introduction. We currently are unable to predict when these efforts will be completed and when revenues from the sale of the MTX-180 and related applicators will begin. We do not believe, however, that these revenues will begin until at least the third or fourth quarter of calendar year 2010. We cannot be assured that our efforts to commercialize the MTX-180 will be successful. If our efforts to commercialize the MTX-180 are not successful, our business will be adversely affected.

Sales of our product could be significantly reduced if government, private health insurers and other third-party payors do not provide sufficient coverage or reimbursement.

Our success in selling our products will depend in large part on the extent to which reimbursement for the costs of our products and related treatments are available from government health agencies, private health insurers and other third-party payers. Despite the existence of general reimbursement policies, local medical review policies may differ for public and private insurance payers, which may cause payment to be refused for some hyperthermia treatments. Private payers also may refuse to pay for hyperthermia treatments.

Medical reimbursement rates are unpredictable and we cannot predict the extent to which our business may be affected by future legislative and regulatory developments. Future health care legislation or regulation may limit our business or impose additional delays and costs on our business and third-party reimbursement may not be adequate to cover our costs associated with producing and selling our products.

Cancer therapy is subject to rapid technological change and therapies that are more effective than ours could render our technology obsolete.

The treatment of cancer is currently subject to extensive research and development. Many cancer therapies are being researched and our products may be rendered obsolete by existing therapies and as a result of therapy innovations by others. If our products are rendered obsolete, our revenue will decline, we may never achieve profitability, and we may not be able to continue in business.

Additionally, other companies, particularly established companies that currently manufacture and sell other cancer therapy systems, could potentially become competitors (in that they are also engaged in cancer treatment business), and they have significantly greater resources than we do.

Some of the medical institutions to which we have sold in the past have not been able to pay for their equipment, and some of our sales have therefore become substantial bad debts, a risk that could continue into the future.

A limited number of our customers have been developing clinics, and these customers have been particularly vulnerable to financial difficulties that can cause them to be unable to pay for equipment that they have purchased. If we choose to accept higher risk sales opportunities to clinics in the future, we will be subject to these customer credit risks that could lower future net sales due to bad-debt write offs, resulting in losses in future periods and potentially lowering the value of our stock. While we attempt to provide for foreseeable doubtful accounts, we cannot assure that this provision will always be adequate to cover our credit risks.

Increasing sales of our hyperthermia systems depends on our ability to successfully expand our sales distribution channels; however, we have had failures with the productivity of new channels of distribution in the past. Expanding our channels of distribution will also significantly increase our sales expenses, which could negatively impact our financial performance.

We believe that the success of our efforts to increase sales of our hyperthermia systems in the future depends on our ability to successfully expand our sales distribution channels. Historically, we have sometimes failed in establishing successful new sales channels.

We anticipate that the success of our multi-year plan for selling hyperthermia systems will require expanding our sales and marketing organization through a combination of direct sales people, distributors and internal and external marketing expertise. However, as we pursue our marketing plan, there can be no assurance that we will be successful in securing reliable channels of distribution to meet our plan through expanded sales. Recruiting and training new

distribution channels can take time and considerable expense. We project that sales and marketing expenses will increase substantially in the future as compared to past years. This added expense could have an adverse effect on our future financial performance that is greater than any potential increases in sales.

In addition, there can be no assurance that our channels of distribution that have been successful in the past will be successful in the future. We have derived a significant portion of our revenue from sales in Europe and in China. Sales in Europe were made through our distributor Medizin-Technik, GmbH, which also purchases equipment components and parts from us. Medizin-Technik is controlled by Dr. Sennewald, one of our directors. The loss or ineffectiveness of either Medizin-Technik or our Chinese distributor as a distributor and significant customer could result in lower revenue.

We may face significant uncertainty in the industry due to government healthcare reform.

In March 2010, Congress passed sweeping healthcare reform in the Patient Protection and Affordable Care Act. We have not been able to assess the impact of the legislation on the Company, but it could result in new taxes on revenues for medical device companies and impact the utilization and reimbursement of our products. Our results of operations, our financial position and cash flows could be materially adversely affected by changes under the new legislation or under any federal or state healthcare legislation adopted in the future.

We are subject to government regulations that can delay our ability to sell our products and cause us to incur substantial expenses.

Our research and development efforts, pre-clinical tests and clinical trials, and the manufacturing, marketing, distribution and labeling of our products are subject to extensive regulation by the FDA and comparable international agencies. The process of obtaining FDA and other required regulatory approvals is lengthy and expensive and our financial resources are limited.

Obtaining pre-market approval or marketing clearance as a 510(k) submission from the FDA is necessary for us to commercially market our systems in the United States. Obtaining approvals is a lengthy and expensive process. We may not be able to obtain these approvals on a timely basis, if at all, and such failure could harm our business prospects substantially. Further, even if we are able to obtain the approvals we seek from the FDA, the approvals granted might include significant limitations on the indicated uses for which the products may be marketed, which restrictions could negatively impact our business. We are unable to predict when the review process will be completed and its ultimate outcome. If we are unable to receive HDE marketing approval, or if the FDA requires us to undergo extensive testing in order to grant HDE marketing approval, our business could be adversely affected.

After a product is approved for commercial distribution by the FDA, we have ongoing responsibilities under the Federal Food, Drug, and Cosmetic Act and FDA regulations, including regulation of our manufacturing facilities and processes, labeling and record-keeping, and reporting of adverse experiences and other information. Failure to comply with these ongoing requirements could result in the FDA imposing operating restrictions on us, enjoining or restraining certain violations, or imposing civil or criminal penalties on us.

All of these laws are subject to evolving interpretations. If the federal government were to conclude that we are not in compliance with any of these health care laws, we could be subject to substantial criminal and civil penalties, and could be excluded from participation as a supplier to beneficiaries in federal health care programs.

We depend on adequate protection of our patent and other intellectual property rights to stay competitive.

We rely on patents, trade secrets, trademarks, copyrights, know-how, license agreements and contractual provisions to establish and protect our intellectual property rights. Our success will substantially depend on our ability to protect our intellectual property rights and maintain rights granted to us through license agreements. Our intellectual property rights may only afford us limited protection and may not adequately protect our rights or remedies to gain or keep any advantages we may have over our competitors, which could reduce our ability to be competitive and generate sales

and profitability.

In the past, we have participated in substantial litigation regarding our patent and other intellectual property rights in the medical device industry. We have previously filed lawsuits for patent infringement against three of our competitors and subsequently settled all three of those lawsuits. Additional litigation against other parties may be necessary in the future to enforce our intellectual property rights, to protect our patents and trade secrets, and to determine the validity and scope of our proprietary rights. This litigation may require more financial resources than are available to us. We cannot guarantee that we will be able to successfully protect our rights in litigation. Failure to successfully protect our rights in litigation could reduce our ability to be competitive and generate sales and profitability.

A product liability settlement could exceed our ability to pay.

The manufacturing and marketing of medical devices involves an inherent risk of product liability. We presently carry product liability insurance with coverage limits of \$3 million. Our product liability insurance does not cover certain liabilities, including without limitation, intended or expected injury, injury of our own employee, injury or damage due to war, damage to property that we own, damage to our work, certain contractual liabilities, product recalls, patent infringements, pollution claims, or injury or damage resulting from asbestos inhalation. We are responsible to pay the first \$10,000 resulting from any claim up to a maximum of \$50,000 in one year. We cannot assure that our product liability insurance will provide adequate coverage against potential claims that might be made against us. If we were to be subject to a claim in excess of our coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim from our limited resources, which would reduce our limited capital resources and liquidity and reduce capital we could otherwise use to obtain approvals for and market our products. In addition, liability or alleged liability could harm our business by diverting the attention and resources of our management and by damaging our reputation.

We are dependent upon key personnel, some of whom would be difficult to replace.

Our success will be largely dependent upon the efforts of Harold R. Wolcott, our President, Paul F. Turner, our Senior Vice President and Chief Technology Officer, and Dixie T. Sells, our Vice President of Regulatory Affairs, and other key employees. We do not maintain key-person insurance on any of these employees. Our future success also will depend in large part upon our ability to identify, attract and retain other highly qualified managerial, technical and sales and marketing personnel. Competition for these individuals is intense. The loss of the services of any of our key personnel, the inability to identify, attract or retain qualified personnel in the future or delays in hiring qualified personnel could make it more difficult for us to manage our business and meet key objectives such as the sale of our products and the introduction of new products.

The market for our stock is limited and our stock price may be volatile.

The market for our common stock has been limited due to low trading volume and the small number of brokerage firms acting as market makers. Because of the limitations of our market and volatility of the market price of our stock, investors may face difficulties in selling shares at attractive prices when they want to. The average daily trading volume for our stock has varied significantly from week to week and from month to month, and the trading volume often varies widely from day to day. The following factors could impact the market for our stock and cause further volatility in our stock price:

announcements of new technological innovations;

FDA and other regulatory developments;

changes in third-party reimbursements;

developments concerning proprietary rights;

third parties receiving FDA approval for competing products; and

market conditions generally for medical and technology stocks.

Our directors and executive officers own a substantial number of shares of our capital stock, which could discourage or prevent a takeover, even if an acquisition would be beneficial to our stockholders.

Our directors and executive officers own approximately 37% of our outstanding voting power. Accordingly, these stockholders, individually and as a group, may be able to influence the outcome of stockholder votes involving the election of directors, the adoption or amendment of provisions in our certificate of incorporation and bylaws and the approval of certain mergers or other similar transactions, such as a sale of substantially all of our assets. Such control by existing stockholders could have the effect of delaying, deferring or preventing a change in control of our company.

Future sales of shares of our securities may negatively affect our stock price.

We are unable to predict the effect, if any, that future sales of common stock, or the availability of our common stock for future sales, will have on the market price of our common shares from time to time. Sales of substantial amounts of our common stock (including shares issued upon the exercise of stock options or warrants), or the possibility of such sales, could adversely affect the market price of our common stock and also impair our ability to raise capital through an offering of our equity securities in the future. In the future, we may issue additional shares or warrants in connection with investments or for other purposes considered advisable by our Board of Directors. Any substantial sale of our common shares may have an adverse effect on the market